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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SORBELLO, ELEANOR

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/427,657

Applicant(s)

ALITALO ET AL.

Examiner

Eleanor Sorbello

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 April 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-18 and 21-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-18 and 21-72 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Response to amendment***

1. Applicant's amendment filed 4/1/02, paper number 14 has been entered.

**Claims 1-8, 10-18, 21-72 are pending.** Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow.

2. Applicant's arguments are addressed below on a per section basis. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

3. Claim 29 stands rejected under 35 USC § 102 (b) as being anticipated by Alitalo; and rejected under 35 USC § 102 (a) as being anticipated by Achen, for reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the examiner admits that the two references cited fail to disclose the label. However, as stated in the previous office action and maintained herein, is that the "label" does not add patentable weight to this invention. Applicant, using the reasoning of the Court decision *In re Miller* argues that the rejection of claim 29 is based on a false premise that instructions do not impart patentable weight. Applicant argues that if the combination of VEGF-C or VEGF-D with instructions provides a new and unobvious functional relationship, then patentable weight is placed on the instructions. However, examiner argues that in this case the printed matter is not

Art Unit: 1632

considered a patentable distinction because the function of the nucleotide sequences encoding VEGF-C or VEGF-D do not depend upon the printed matter itself, which is not a part of the product or device. Examiner argues that the instantly claimed kit comprising, the nucleotides encoding VEGF-C or VEGF-D do not lose their function without the printed label. The components of the kit remain fully functional absent the printed instructions for use. This is in sharp contrast to the beaker with markings in half quantities, in the *In re Miller* case that applicants were drawing an analogy to. Thus the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03:

Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey* 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, applicant argues that the claims are drawn to a kit comprising instructions and VEGF-C or VEGF-D polynucleotides operably linked to a promoter wherein the claim recites that the label describes the use of the aforesaid for the inhibition of restinosis. Alitalo and Achen disclose polynucleotides encoding VEGF-C or VEGF-D. Alitalo explicitly states that VEGF-C shares a redundant function with VEGF in angiogenesis. (See page 30 lines 22-25).

Applicant also argues that *In re Miller* expresses the notion of functionality that the courts have recently addressed in software and business method patents.

Art Unit: 1632

Applicants argue that like the instructions direct a machine to perform a useful result, the label of claim 29 converts the VEGF-C or VEGF-D kit into a useful tool for the treatment of restinosis. However, examiner argues that the claim does not list any specific instructions or dosages as stated by applicants. The claim simply recites that the kit comprises a label attached to the package and that it describes the use of the nucleotides for the inhibition of restinosis. Therefore, as stated before, "the instructions" in this case failed to describe any specifics novel to the invention.

Therefore, the intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

### ***Claim Rejections - 35 USC § 103***

4. Claims 1-6, 10-18, 22-32, 49-58, 63-69, 71, 72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Isner (U. S Pat. No: 5,652,225 and 5,830,879 ) in view of Alitalo (W/O 97/05250), for reasons of record.

Applicants argue that Isner purports to disclose a method of delivery of a nucleic acid to an arterial cell, and that the central purpose in the disclosed method, is that of

Art Unit: 1632

using a hydrophilic polymer incorporating the nucleic acid, instead of the double balloon catheter.

Applicants further argue the Alitalo patent purports to teach a method for the treatment of blood vessels that have been injured, by using VEGF.

However, examiner argues that applicants are considering each reference individually, and that the 103 rejection is based on the combination of the references based on the knowledge available at the time of the invention which provides a motivation to combine the references.

Applicants argue that there would have been no motivation to combine the references because VEGF was not structurally or functionally similar to VEGF-C or VEGF-D. However, examiner argues that VEGF as taught by Isner is for the formation of new blood vessels. Examiner argues that restenosis is a mechanism of overcoming a blocked artery, that may be accomplished by the formation of new blood vessels to by pass the clogged artery. Therefore, examiner argues in response to applicant's argument that the intended result of restenosis or new blood vessel formation results in the same end result. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Alitalo explicitly states that VEGF-C shares a redundant function with VEGF in angiogenesis. (See page 30 lines 22-25). Therefore although applicants argue that it would not have been obvious to substitute VEGF-C or VEGF-D for VEGF in a method of treating a mammalian subject to inhibit

Art Unit: 1632

restenosis, as argued herein one of ordinary skill would have been motivated to make the substitutions because of the teachings in the prior art, and the intended use of by-passing a clogged artery or providing a treatment for restenosis, accomplished by VEGF-C or VEGF-D.

5. Claims 21-51, 57-69, 71-72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Isner (U. S Pat. No: 5,652,225 and 5,830,879 ) in view of Achen et al.(WO 98/07832).

Applicants arguments are the same and argue that due to the differences in structure and function of VEGF and VEGF-C or VEGF-D, one of ordinary skill would not have been motivated to combine the teachings in the prior art to come up with the instant invention.

The examiner rebuts applicants argument as discussed above.

6. Claims 1-6, 10-18, 22-72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over **either** Isner in view of Alitalo as applied to claims 1-6, 10-18 above, **or** Isner in view of Achen as applied to claims 21, 33-48 **and** further in view of Martin et al (WO 98/20027, Published 14 May, 1998).

Applicants arguments are the same and they argue that due to the differences in structure and function of VEGF and VEGF-C or VEGF-D, one of ordinary skill would not have been motivated to combine the teachings in the prior art to come up with the instant invention.

Art Unit: 1632

The examiner rebuts applicants argument as discussed above.

#### Conclusion

7. Claims 1-6, 10-18, 21-72 are rejected for the reasons set forth above.
8. Claims 7, 8 are objected to for depending on rejected claims.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 308-0009.



Art Unit: 1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.

Eleanor Sorbello

  
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